

Global Study Manager/Sr. Global Study Manager

Job ID: 00413585

Job Function

Clinical Operations

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Experienced

Who We Are

At the Roche Group, about 80,000 people across 150 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world's leading research-focused healthcare groups. A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 30 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. The headquarters for Roche pharmaceutical operations in the United States, Genentech has multiple therapies on the market for cancer and other serious illnesses. Please take this opportunity to learn about Genentech, where we believe that our employees are our most important asset and are dedicated to remaining a great place to work.

The Position

Provides the operational expertise and leadership to one or more clinical operations teams to ensure the effective and efficient delivery of all operational aspects of one or more studies through all phases of Clinical Study Management (Plan, Initiate, Conduct, Close), in accordance with the appropriate quality standards including ICH/GCP and applicable regulations.

Main Responsibilities and Accountabilities:

- Provides direction and leadership to one or more clinical operations teams
- Develops operational plans including site monitoring strategies, risk mitigation strategies, trial budgets, site selection, and clinical supplies management.
- Builds effective and efficient high performing operations teams and ensures team members are aware of their accountabilities, responsibilities and deliverables.
- Creates team culture and promotes team spirit.
- Develops and maintains effective working relationships with SMT members, with particular focus on affiliate teams, external CRO (for outsourced teams) and co-development partner study teams.
- In collaboration with functional management, coaches, mentors, supports, and provides study specific direction to Study Management team members.
- Oversees the development and maintenance of study specific manuals created by the

GSA.

- Contributes to the development and management of the study timelines, resources, budget, risk and quality plans
- Ensures operational tracking tools are identified, including systems to meet the needs of the operations team and ensures reporting to the GSL.
- Develops and manages clinical study budgets (including HQ budget) and contributes to staffing/resourcing plans. Communicates variances in the budget and action plan for resolution to the GSL.
- Establishes study milestones and ensures accurate tracking and reporting of study metrics.
- Provides operational input into the development of protocol feasibility questionnaires.
- Provides clinical operations expertise to ensure operational feasibility and delivery
- Leads the development and finalization of site feasibility questionnaires.
- Leads the creation of the study level patient recruitment plan and retention strategies based on feasibility data and input from the affiliate teams and consultation with the GSL and OPL.
- Provides operational input and insight into all study related documentation (including protocol and informed consent form) and processes.
- Analyzes the feasibility data across countries with input from the affiliates and makes recommendations to the GSL for the strategic country and site distribution and patient numbers.
- Oversees forecasting of clinical/non-clinical supplies
- Designs drug assumption and supply chain process in partnership with Pharma Technical Drug Supplies, affiliates and GSL.
- Oversees the forecasting and management of non-clinical supplies to ensure sites have supplies to run clinical study.
- Delivers the operational elements of the study plan
- Chairs operations team meeting and organizes the investigator meetings, monitor training, CRO kick-off meetings.
- Ensures that reporting of SUSARs is established and maintained for the duration of the study.
- Proactively manages actual study level recruitment versus planned patient recruitment status and communicates variance to the GSL and implements contingencies in consultation with the GSL.
- Primary contact with affiliates to maintain oversight of performance, issues, and their resolution and identify systematic issues and coordinates any corrective action.
- Ensures the completion and finalization of any corrective and preventative action plans resulting from internal site audits.
- Oversees the maintenance of drug supplies and resolution of issues with input from the Pharma Technical Drug Supplies.
- Coordinates responses to study questions or issues from Health Authorities or IRBs/IECs.
- Provides operational input into the development and tracking of SMT goals.
- Provides the day-to-day operational management of CROs and vendors to ensure delivery against contracted scope of work
- Performs ongoing vendor management (e.g., CROs, Central Labs, IVRS, Reading Centers), including independent negotiation of scope of work, budgets, performance management, and issue resolution.
- Develops and executes appropriate site and CRO/vendor audit and quality plans.
- Identifies areas of best practice and process improvements
- Participates in Pharma Development Operations initiatives and programs as assigned.
- Maintains oversight and ensures consistency of the operational aspects across studies within a project.

- Ensures study adherence to ICH/GCP and SOPs

Who You Are

Qualifications:

Life sciences degree or nursing equivalent or substantial experience in a clinical research/a healthcare environment.

Skills & Knowledge:

Experience

- Proven clinical development experience of the operational aspects of all stages of clinical studies preferably working in a Global environment and/or including monitoring or leading affiliate teams, working with vendors and/or CROs, drug supply management and planning operational activities to achieve database lock.
- Experience of project managing operational aspects of a clinical study including development of timelines, budgets and resource plans.
- Good knowledge of ICH GCP
- Proven ability to successfully achieve results within a multi-cultural and geographically diverse team.
- Experience of working as part of a large team and leading small study or functional teams, with a proven ability to be an active member of the team and motivate and lead a small team to deliver against commitments.
- Well developed written and verbal communication skills demonstrated by an ability to present clear instruction/direction to teams at the same level in the organization and influence at higher levels in the organization.

Competencies

- Project Management
- Collaboration and Teamwork
- Negotiating
- Communication
- Personal Organization *LI-EK1

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